Vivoryon Therapeutics N.V.

WKN: A2QJV6 **ISIN:** NL00150002Q7 **Land:** Deutschland

Nachricht vom 28.04.2022 | 07:00

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DGAP-News: Vivoryon Therapeutics N.V. / Key word(s): Annual Results/Annual Report
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28.04.2022 / 07:00
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Vivoryon Therapeutics N.V. Reports Full Year 2021 Financial Results and Highlights Operational Progress

Substantial progress in clinical development of QPCT/L inhibitor varoglutamstat, EU and U.S. clinical studies in AD on track
FDA Fast Track designation for lead product candidate in AD
Partnered clinical development of varoglutamstat in China under strategic regional licensing partnership with Simcere approved to proceed
Preclinical evidence supporting rationale for evaluating varoglutamstat in combination with Abeta antibodies
EUR 21 million raised in successful private placement to support ongoing clinical development

Halle (Saale) / Munich, Germany, April 28, 2022 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**)), a clinical stage company focused on discovery and development of small molecule medicines to modulate the activity and stability of pathologically altered proteins, today announced financial results for the twelve month period ending December 31, 2021 and provided an update on its corporate progress. The report is available on the Company's website https://www.vivoryon.com/investors-news/financial-information/

"2021 was a truly outstanding year for Vivoryon, marked by a number of hugely important achievements in the clinical development of our lead candidate varoglutamstat for the treatment of Alzheimer's disease. Despite the pandemic-related challenges, we have met the recruitment objectives for our European Phase 2b VIVIAD study and initiated our Phase 2a/b study VIVA-MIND in the U.S. as planned. Clinical development in the U.S. is further supported by the Fast Track designation the FDA has granted for varoglutamstat last December. In addition, the regulatory achievements of our Chinese partner Simcere, enabling near-term clinical development in China, broadens the tremendous opportunity we have to make varoglutamstat available to as many patients as possible. All of these highlights are a testimony to our team's unwavering dedication to making a difference for those affected by Alzheimer's disease worldwide," said Dr. Ulrich Dauer, CEO of Vivoryon. "As an oral small molecule designed to target all hallmarks of AD, varoglutamstat is truly differentiated from all other approaches and we are convinced that its unique mode of action positions it as an urgently needed alternative to solely Abeta-focused, antibody-based treatments. For the remainder of the year, we are looking at a number of key milestones and inflection points that we believe will further substantiate the potential of varoglutamstat in AD. The successful placement of new shares amounting to EUR 21 million at the beginning of April this year, with participation of a number of high-quality institutional investors from Europe and the U.S., will enable us to reach these milestones, and we are extremely grateful to all our shareholders for their continued support."

Clinical Portfolio Highlights

In December, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for Vivoryon's lead product candidate varoglutamstat. Varoglutamstat, an oral QPCT/L inhibitor, is the Company's lead product candidate and the first small molecule and only project in clinical development selectively targeting the *de novo* production of neurotoxic N3pE amyloid, a toxic Abeta variant shown to play a pivotal role in the development and progression of Alzheimer's disease (AD). Fast Track is a process designed to facilitate the development, and expedite the review of drugs with the potential to treat serious conditions and fill an unmet medical need, aiming to bring important new drugs to the patient earlier. With Fast Track designation, the development of varoglutamstat can benefit from more frequent engagement with the FDA to discuss varoglutamstat's development plan and ensure collection of the appropriate data needed to successfully advance varoglutamstat through clinical development.

In September 2021, Vivoryon initiated its U.S. Phase 2a/b VIVA-MIND study (NCT03919162) for varoglutamstat in patients with early AD. VIVA-MIND is a combined Phase 2a/b study which seeks to enroll 180 patients into the Phase 2a adaptive dose finding part. If predefined criteria are fulfilled, the trial will pass a stage-gate into the Phase 2b part, enrolling an additional 234 patients treated at the selected dose for at least 72 weeks. Thus, taken together a total of 414 patients will be treated on stable doses of varoglutamstat for 18 months in the course of the study. The primary endpoint for this study is CDR-SB (clinical dementia rating scale - sum of boxes), an established approvable endpoint measuring a combination of cognitive abilities and activities of daily living. The study is coordinated by the Alzheimer's Disease Cooperative Study (ADCS), and supported by a US$15 million grant from the National Institute on Aging (NIA award number R01AG061146). The study is actively enrolling patients, with currently eleven sites open and on track for an interim futility analysis planned for the first half of 2023.

Vivoryon's ongoing European VIVIAD study (NCT04498650) is a state-of-the-art Phase 2b study designed to yield important results in early AD for varoglutamstat. Mitigating the effects of the ongoing pandemic, Vivoryon has more than doubled the originally planned number of study centers. The study is enrolling a total of 250 patients with mild cognitive impairment (MCI) and mild AD. Objectives are to evaluate the long-term efficacy (primary endpoint subset of Cogstate NTB), safety and tolerability of oral varoglutamstat. The first 90 patients are randomised 1:1:1 (600 mg twice daily, (BID) or 300 mg BID varoglutamstat or placebo BID). An independent data safety monitoring board (DSMB) will unblind safety results after 90 patients have completed 24 weeks of treatment and select the final varoglutamstat dose to be carried forward for the remainder of the study. Here, all patients will be randomized 1:1 between the final dose of varoglutamstat and placebo and continue treatment up to 48-96 weeks dependent on their study entry date. In addition to the full composite Neuropsychological Test Battery (NTB) score administered throughout the study to assess cognition, a set of exploratory read-outs including cognitive tests, functional electroencephalogram (EEG), magnetic resonance imaging (MRI) assessments and the analysis of new molecular biomarkers in the cerebrospinal fluid (CSF) will be used to evaluate the compound's effect on disease pathology. Secondary endpoints include long-term safety and tolerability of varoglutamstat and its effect on brain activity, cognition and activities of daily living. Details on the study background and design were published in the Journal "Alzheimer's Research & Therapy" (Vijverberg et al., https://doi.org/10.1186/s13195-021-00882-9). With 22 active study sites VIVIAD remains on track for an interim safety readout in mid-22 and Vivoryon continues to anticipate final data in the second half of 2023.

Further substantiating the rationale for evaluating varoglutamstat in combination with monoclonal antibodies to treat AD, in October 2021, Vivoryon and its collaboration partners published data providing strong preclinical evidence of treatment with a combination of the Company's small molecule QPCT/L inhibitor varoglutamstat and its N3pE amyloid-specific antibody PBD-C06 having an additive effect on reducing brain Abeta pathology in transgenic mice. The data, published in the "International Journal of Molecular Sciences" (Hoffmann et al., https://doi.org/10.3390/ijms222111791), support the hypothesis of a potential benefit of a combination therapy designed to simultaneously target two different and independent molecular pathways, namely reducing N3pE amyloid production by QPCT/L inhibition and clearing existing Abeta deposits through anti-N3pE-immunotherapy.

Also in October 2021, the Company announced the expansion of its manufacturing capabilities for production of active pharmaceutical ingredient (API) by initiating a second line of manufacturing with an additional partner to ensure sustainable study drug supply with varoglutamstat for VIVA-MIND beyond the ongoing Phase 2a adaptive dose finding part, as well as for potential future studies in other geographies, with the added benefit of increasing flexibility to react to global challenges such as the ongoing pandemic.

Corporate Development Highlights

In June 2021, Vivoryon and Simcere Pharmaceutical Group Ltd entered into a strategic regional licensing partnership to develop and commercialize medicines targeting the neurotoxic amyloid species N3pE (pGlu-Abeta) to treat AD in Greater China. The agreement grants Simcere a regional license to develop and commercialize varoglutamstat (PQ912), Vivoryon's Phase 2b-stage N3pE amyloid-targeting oral small molecule glutaminyl cyclase (QPCT) inhibitor with disease-modifying potential for AD, as well as the Company's preclinical monoclonal N3pE antibody PBD-C06 in the Greater China region.

In March 2021, the Extraodinary General Meeting of Vivoryon re-appointed Dr. Ulrich Dauer as CEO and appointed Florian Schmid as CFO as of April 1, 2021. Mr. Schmid joined Vivoryon from InflaRx, where he served as Director Finance & Controlling. In Vivoryon's 2021 Ordinary Annual General Meeting held June 28, 2021, all items presented for resolution by the Board of Directors were

approved with a large majority, including the re-appointment of Dr. Michael Schaeffer as CBO.

Throughout 2021, Vivoryon further expanded its patent portfolio with a total of 55 additional patents that have been granted from January to December for the Company's small molecule inhibitors and antibody-based medicines in development to treat AD and other diseases with exceptionally high medical need.

Post-period Events

On April 1, 2022, Vivoryon announced that it had successfully completed a private placement by way of accelerated bookbuilding, raising gross proceeds of EUR 21 million. The Company placed 2,000,000 registered shares at an offering price of EUR 10.50 per share. The new shares from the capital increase represent 10% of Vivoryon's existing issued share capital and have been issued from the Company's authoritzed capital under exclusion of the existing shareholders' pre-emptive rights. As a consequence, the Company's issued share capital has increased to EUR 22,050,482.00. Vivoryon intends to use the net proceeds from the offering to support the ongoing clinical development of its lead candidate varoglutamstat, as well as for general corporate purposes. The new shares have been admitted to trading on Euronext Amsterdam on April 5, 2022. The capital raise was supported by a number of high-quality institutional investors from Europe and the U.S. as well as members of Vivoryon's Executive and Non-Executive Boards.

On February 28, 2022, Vivoryon and its partner Simcere announced that China's Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) has approved the Clinical Trial Application for varoglutamstat for the development in Greater China by Simcere. Simcere intends to start the clinical Phase 1 study in China in the first half of 2022.

In line with the Company's efforts to meet international best practice standards, Vivoryon plans to expand and diversify its Non-Executive Board, intending to propose two additional candidates for nomination at its 2022 Annual General Meeting to be held later this year.

Financial Results for the Full Year 2021

The Company generated **license revenues** of EUR 10.8 million in 2021 from a regional licensing partnership with Simcere Pharmaceutical Group Ltd for Greater China (Mainland China, Hong Kong, Macao and Taiwan) signed on June 29, 2021. No revenues were generated in 2020, respectively.

Research and development expenses increased in 2021 by EUR 4.2 million compared to the year ended December 31, 2020. This increase is primarily attributable to a EUR 3.7 million higher expenses for our clinical trial, VIVIAD, and the related production of PQ912, as well as EUR 0.8 million higher expenses for share-based payments.

General and administrative expenses increased by EUR 1.7 million largely attributable to EUR 0.8 million higher expenses for share based payments as well as EUR 0.6 higher expesenses for legal and consulting services in connection with preparation of a US listing.

Net loss for the twelve months ended December 31, 2021 was EUR 12.7 million, compared to EUR 16.5 million for the twelve months ended December 31, 2020. The Company held EUR 14.7 million in cash and cash equivalents as of December 31, 2021, compared to EUR 26.3 million as of December 31, 2020.

Financial Guidance

Following the capital raise completed in April 2022, according to current planning and estimates, Vivoryon expects that its existing cash and cash equivalents will be sufficient to fund its research and development expenses as well the general and administrative expenses and cash flows from investing and financing activities at least through end of May 2023. This guidance does not include potential milestone payments from development partnerships, potential payments from licensing agreements and/or additional financing measures, as far as such payments have not yet been recognized in revenues. The financial guidance takes into account all costs to ensure sustainable study drug supply with varoglutamstat for the VIVA-MIND U.S. study.

Vivoryon Therapeutics N.V. Financial Statements

Statement of Profit or Loss and Other Comprehensive Income for the Years Ended December 31, 2021 and 2020

in kEUR, except for share data	**2021**	**2020**

Revenue	10,764	-
Cost of Sales	(1,569)	-
Gross profit	**9,196**	**-**
Research and development expenses	(17,452)	(13,210)
General and administrative expenses	(4,549)	(2,807)
Other operating income	7	6
Operating loss	**(12,798)**	**(16,011)**
Finance income	967	105
Finance expense	(392)	(604)
Finance result	**575**	**(499)**
Result before income taxes	**(12,223)**	**(16,510)**
Income taxes	(432)	-
Net loss for the period	**(12,655)**	**(16,510)**
Items not to be reclassified subsequently to profit or loss		
Remeasurement of the net defined benefit pension liability	83	(93)
Total other comprehensive income / (loss)	83	(93)
Comprehensive loss	**(12,572)**	**(16,603)**
Loss per share in EUR (basic and diluted)	(0.63)	(0.83)

The accompanying notes are an integral part of these financial statements.

Vivoryon Therapeutics N.V.
Statements of Financial Position as December 31, 2021 and 2020

in kEUR	**2021**	**2020**
ASSETS		
Non-current assets		
Intangible assets	533	565
Property, plant and equipment	66	80
Right-of-use assets	219	310
Financial assets	3,473	3
Total non-current assets	**4,291**	**958**
Current assets		
Financial assets	3,074	21
Other current assets and prepayments	2,494	2,487
Cash and cash equivalents	14,661	26,306
Total current assets	**20,229**	**28,793**
TOTAL ASSETS	**24,520**	**29,751**
Equity		
Share capital	20,050	19,975
Share premium	83,211	82,143
Other capital reserves	6,168	4,404
Accumulated other comprehensive loss	(572)	(655)
Accumulated deficit	(92,300)	(79,646)
Total equity	**16,557**	**26,221**
Non-current liabilities		
Pension liability	1,823	1,981
Provisions long-term	12	-
Lease liabilities	132	224
Other liabilities	513	-
Deferred tax liabilities	432	-
Total non-current liabilities	**2,912**	**2,205**
Current liabilities		
Provisions	35	47
Trade payables	4,360	911
Lease liabilities	92	90
Other liabilities	564	276
Total current liabilities	**5,051**	**1,325**
Total Liabilities	**7,963**	**3,530**
TOTAL EQUITY AND LIABILITIES	**24,520**	**29,751**

Vivoryon Therapeutics N.V.
Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2021 and 2020

in kEUR	Share capital	Share premium	Other capital reserves	Accumulated other compre-hensive loss	Accumulated deficit	Total equity
January 1, 2020	**19,975**	**82,143**	**4,245**	**(562)**	**(63,136)**	**42,665**

Net loss for the period	-	-	-	-	(16,510)	(16,510)
Remeasurement of the net defined benefit pension liability	-	-	-	(93)	-	(93)
Comprehensive income / (loss)	**-**	**-**	**-**	**(93)**	**(16,510)**	**(16,603)**
Share-based payments	-	-	159	-	-	159
December 31, 2020	**19,975**	**82,143**	**4,404**	**(655)**	**(79,646)**	**26,221**
Net loss for the period	-	-	-	-	(12,655)	(12,655)
Remeasurement of the net defined benefit pension liability	-	-	-	83	-	83
Comprehensive income / (loss)	**-**	**-**	**-**	**83**	**(12,655)**	**(12,572)**
Share-based payments	-	-	1,763	-	-	1,763
Proceeds from exercise of share options	75	1,069	-	-	-	1,144
December 31, 2021	**20,050**	**83,211**	**6,168**	**(572)**	**(92,300)**	**16,557**

Vivoryon Therapeutics N.V.
Statements of Cash Flows for the Years ended December 31, 2021 and 2020

in kEUR	**2021**	**2020**
Operating activities		
Result before income taxes	(12,223)	(16,510)
Adjustments for:		
Finance result	(575)	499
Depreciation and amortization	165	146
Share based payments	1,763	159
Other non-cash adjustments	178	(5)
Changing in		
Financial assets	(6,522)	310
Other current assets and prepayments	1,852	1,056
Pension liabilities	(158)	(80)
Provisions	-	35
Trade payables	3,449	372
Other liabilities	800	(12)
Interest received	21	26
Interest paid	(7)	(7)
Taxes paid	-	-
Cash flows used in operating activities	**(11,257)**	**(14,012)**
Investing activities		
Purchase of plant and equipment	(20)	(64)
Purchase of intangible assets	(8)	(576)
Cash flows used in investing activities	**(28)**	**(640)**
Financing activities		
Capital raising costs	(1,881)	-
Payment of lease liabilities	(90)	(90)
Proceeds from exercise of share options	1,144	-
Cash flows provided by /(used in) financing activities	**(827)**	**(90)**
Net decrease in cash and cash equivalents	**(12,112)**	**(14,742)**
Cash and cash equivalents at the beginning of period	26,306	41,524
Effect of exchange rate fluctuation on cash held	467	(476)
Cash and cash equivalents at the end of period	**14,661**	**26,306**

Annual Financial Report 2021
The financial statements of Vivoryon have been prepared in accordance with International Financial Reporting Standards (IFRS) of the International Accounting Standards Board, as adopted by the European Union (EU-IFRS) and with Section 2:362(9) of the Netherlands Civil Code. The auditor KPMG has issued an unqualified auditor's report for both statements. The reports are available on the Company's website (https://www.vivoryon.com/investors-news/financial-information/).

Conference Call and Webcast
Vivoryon will host a conference call and webcast today, April 28, 2022, at 3:00 pm CEST (09:00 am EDT). A Q&A session will follow the presentation of the full year results.

Please dial one of the following access numbers:
From Germany: +49 69 201 744 220
From The Netherlands: +31 207 168 020
From Switzerland: +41445806522
From UK: +44 20 30 092 470
From the U.S.: +1 877 423 08 30

PIN Code: 84537239#

Please dial in ten minutes prior to commencement.
A live webcast and slides will be made available at: www.vivoryon.com/investors-news/news-and-events/presentations-webcasts/

Approximately one day after the call, a slide-synchronized audio replay of the conference will be available on: www.vivoryon.com/investors-news/news-and-events/presentations-webcasts/

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About Vivoryon Therapeutics N.V.
Vivoryon is a clinical-stage biotechnology company focused on developing innovative small molecule-based medicines. Driven by our passion for ground-breaking science and innovation, we strive to change the lives of patients in need suffering from severe diseases. We leverage our in-depth expertise in understanding post-translational modifications to develop medicines that modulate the activity and stability of proteins which are altered in disease settings. Beyond our lead program, varoglutamstat, which is in Phase 2 clinical development to treat Alzheimer's disease, we have established a solid pipeline of orally available small molecule inhibitors for various indications including cancer, inflammatory diseases and fibrosis. www.vivoryon.com

Vivoryon Forward Looking Statements
This press release includes forward-looking statements, including, without limitation, those regarding the business strategy, management plans and objectives for future operations of the Vivoryon Therapeutics N.V. (the "Company"), estimates and projections with respect to the market for the Company's products and forecasts and statements as to when the Company's products may be available. Words such as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "project," "predict," "should" and "will" and similar expressions as they relate to the Company are intended to identify such forward-looking statements. These forward-looking statements are not guarantees of future performance; rather they are based on the Management's current expectations and assumptions about future events and trends, the economy and other future conditions. The forward-looking statements involve a number of known and unknown risks and uncertainties. These risks and uncertainties and other factors could materially adversely affect the outcome and financial effects of the plans and events described herein. Actual results, performance or events may differ materially from those expressed or implied in such forward-looking statements and from expectations. As a result, no undue reliance should be placed on such forward-looking statements. This press release does not contain risk factors. Certain risk factors that may affect the Company's future financial results are discussed in the published annual financial statements of the Company. This press release, including any forward-looking statements, speaks only as of the date of this press release. The Company does not assume any obligation to update any information or forward-looking statements contained herein, save for any information required to be disclosed by law.

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Additional features:

File: FY 2021 Vivoryon Therapeutics

Language: English
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Listed: Regulated Unofficial Market in Berlin, Frankfurt, Munich, Stuttgart; Amsterdam
EQS News ID: 1337613

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